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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,860	02/20/2004	Gregory James Roger	P67315US1	1645

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EXAMINER

LEWIS, RALPH A

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/781,860		ROGER	
	Examiner		Art Unit	
	Ralph A. Lewis		3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Objection to Drawings

Figures 2a, 3b, 4b and 6 are objected to for illustrating the socket member 10, 101 in cross-section as being comprised of metal when the specification (page 13, line 11) indicates that the socket member is made of ceramic and polymeric materials. See MPEP page 600-95 (section 608.02) for proper cross hatching.

Figures 6 and 7 are objected to under 37 CFR 1.84 (i) and (p) as being informal. The lines, numbers and letters lack uniformity and are fuzzy lacking sharp definition. No new matter should be entered.

Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Misnumbered Claims

There are two different claims numbered "23." The second numbered claim "23" has been renumbered "24" and claims 24-31 have been renumbered 25-32, consecutively. The claims are hereinafter referred to by their new numbers.

Objection to the Claims

Claim 1 is objected under 37 CFR 1.75(i) for lacking a line indentation for each element of the claimed device.

Objections to the Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification provides no apparent basis for the changing modulus of elasticity in claim 16 or the dopings of bioactive material in claim 17.

Rejections based on 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to explain what is meant by “functionally graded or biologically graded material” or give any examples as to what might constitute such materials. There appears to be no basis in the disclosure regarding the changing modulus of elasticity or how such is accomplished. Finally, there is no disclosure as to dopings or what constitutes bioactive material.

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 24 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear what elements are included in the claimed "device." More particularly, while the "bearing member" is positively claimed as part of the invention, it is unclear if applicant is intending to positively claim the bone engaging member and the "line". The examiner suggests structuring the claim in a more conventional manner - such as

"... the device comprising:

a bearing member,

a bone engaging member having a recess, said bearing member at

least partially received within the recess of the bone engaging member,

a liner, said liner being . . . "

In claim 7, there is no antecedent basis for "the at least one screw hole." It appears as though claim 7 should be dependent on claim 6.

In claims 18 and 24, the "preferably" limitation is not understood. Does a .75mm diameter meet the requirements of the claim or does it not?

In claim 32, the "replaces" limitation is not understood.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 19-23, 25, 26 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheldon et al (US 6,475,243).

Sheldon et al disclose in Figure 7 a device comprised of a bearing member 80, bone engaging member 22 having screw holes 28 for securing the bone engaging member to the bone, and a liner 60 positioned between the bearing member 80 and bone engaging member 22. In regard to claim 9, note lip 100. In regard to the titanium limitation of claim 9, note column 7, lines 6 and 7. In regard to claim 13, note column 5, lines 33 and 34.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al (US 6,475,243).

In regard to claims 15-17, to the extent that applicant's specification teaches one of ordinary skill in the art or "functionally graded or biologically graded material" that the modulus of elasticity of the bone engaging member may be varied and the use of dopings with bioactive materials, then such a skilled artisan would have found the use of such prior art elements in the Sheldon et al device to have been obvious. In regard to claims 18 and 19, the specifically claimed width dimension falls within a range one of ordinary skill in the art would have found obvious in constructing the Sheldon et al liner. Finally in regard to claim 27, the use of conventional cold welding to secure the Sheldon et al pieces together would have been obvious to one of ordinary skill in the art as an obvious selection of a conventional prior art attachment.

Prior Art


Applicant's information disclosure statement of September 10, 2004 has been considered and an initialed copy enclosed herewith.

Gilberty (US 3,813,699), Gilberty (US 3,982,281), Haber (US 4,892,551), Schryver (US 5,226,917), Mikhail (US 5,480,448), Pfaff et al (US 5,725,589), Harris (US 6,248,132), Serbousek (US 6,610,097), Arfiat et al (US 6,811,569), and Lewis et al (US 6,926,740) are made of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
September 29, 2006



Ralph A. Lewis
Primary Examiner
Au3732